REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3, 4, 7 and 9-13 are pending in this application. The elements of claims 2, 7, 9, 10 and 11 have been inserted into claim 1. Claims 5, 6 and 8 have been cancelled. New claims 12 and 13 have been added which split a) and b) from claim 1 into separate dependent claims. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE OBJECTIONS TO THE CLAIMS HAVE BEEN OVERCOME

The objections to claims 1-11 have been overcome in light of the above amendments.

III. THE 35 U.S.C. 112, 1st PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 5-10 were rejected as allegedly lacking adequate written description. While the applicants disagree with this rejection, in order to advance prosecution, the applicants have amended the recitation of derivatives to refer to salt forms (for claims 6, 9 and 10) which are notorious to those of skill in the art; claims 5, 6 and 8 have been cancelled which renders this rejection moot. The applicants reserve the right to further prosecute the scope of the originally filed claims in a continuation application.[1]

Claim 6 was rejected as allegedly failing to comply with the enablement requirement. This rejection has been rendered moot by the cancellation of claim 6. The applicants reserve the right to further prosecute the scope of the originally filed claims in a continuation application.

[1] A search of the U.S. Patent database for the term "derivative$" in the claims resulted in 65,012 hits as of 27 October 2008.

IV. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 1-11 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention for using relative terms. While the applicants disagree with these characterizations, in order to advance prosecution, claim 1 has been amended to refer to release of active compound in the oral cavity. The applicants reserve the right to further prosecute the scope of the originally filed claims in a continuation application.

Claims 5-10 were rejected for the use of the term "derivative/derivatives". This rejection is addressed above in section III. of this response.

V. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

A. Claims 1-5 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel")**; Weete et al. (U.S. Patent 5,703,255 – **"Weete")**, *Steadman's Medical Dictionary* (Lippinicott & Wilkins, 2000; accessed online 5/13/2008 – **"Steadman")**; and by Raisch et al. (Ann. Pharmacother., 2002 February; 36(2): 312-321 – **"Raisch")**. The applicants request reconsideration of this rejection for the following reasons.

In order to establish obviousness, all of the claim elements must be taught and suggested by the combination of references and both the applicants claims and the cited references must be considered as a whole. However, the combination of Zhang, Patel, Weete, Steadman and Raisch does not meet this standard for establishing obviousness. (Raisch was cited in the rejection, but its reliance thereon was not clear from a reading of the Office Action)

Zhang does not teach or suggest the applicants' claim 1 as originally filed

Claim 1 as amended now includes the element of originally filed claim 2, however, the applicants dispute certain aspects of the rejection to claim 1, in particular the characterization that lecithin is "commonly accepted to consist almost entirely of phosphatidylcholine." The definition provided by Steadman is not representative of the commonly accepted definition of lecithin which would include other compounds besides phosphatidylcholine which is not surprising as it is a medical dictionary and not a dictionary related to pharmaceutical compositions or uses thereof as in Zhang's or the applicants' invention.

The *Fiedler Encyclopedia of Excipients for Pharmaceuticals, Cosmetics and Related Areas (6th edition)*[2] is more representative of the definition and clearly show that lecithins not only contain phosphatidylcholine, but also other components, e.g. lecithins obtained from hens eggs or soybeans both contain about 35-45% fats and as can be seen from the excerpts from the different sources of lecithin (e.g. soy, cotton, egg and peanut), a large amount of unsaturated fatty acids (i.e. the fatty acid residues are not "at least 90% saturated" as in the applicants' claim) are also part of the composition.

Even a generic sources of information recognize that phosphatidylcholines contain other compounds. (See for example the listing of phosphatidylcholine from Wikipedia – "Phosphatidylcholines are such a major component of lecithin, that, in some contexts, the terms are sometimes synonyms. However, lecithin extract consists of a mixture of phosphatidylcholine and other compounds."). There is no indication that Zhang intended lecithin to be equivalent to phosphatidylcholine especially when a more relevant definition from a pharmaceutical dictionary teaches otherwise.[3]

Therefore, the support for obviousness already fails with the analysis of Zhang because this reference does not teach planiform transmucosal pharmaceutical administration form with the requisite element that the phosphatidylcholine fraction in which the fatty acid residues are at least 90% saturated.

Zhang and Patel do not teach or suggest claim 1 as amended

Claim 1 as amended now include the element from original claim 2 that "the administration form comprises at least 80% by weight of the phosphatidylcholine fraction."

While claim 1 is unobvious for the reasons cited above, the applicants also note that Patel was not suitable for combination with Patel when reading the publication as a whole. Patel is referred to as teaching the use of hydrogenated lecithin, but this is a mischaracterization of Patel's invention as a whole.

At best, Patel refers to a solid pharmaceutical composition which comprises of a pharmaceutically active agent, hydrophilic surfactant, lipophilic surfactant and triglycerides.

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[2] Copy of *Fiedler* is provided as part of an Information Disclosure Statement filed concurrently with this response

[3] These definitions are also consistent with the reference to "hydrogenated lecithins" which was made on page 11, line 5 of the Office Action when referring to the Patel reference. (Patel states on col. 31, line 23 ---***lecithins*** or hydrogenated lecithins---, ***NOT "phosphatidylcholine*** and hydrogenated lecithins" as asserted in the Office Action)

Patel recites a virtual laundry list of each of these elements of their invention and as such one of ordinary skill in the art would not have specifically been drawn to the use of phosphatidylcholines as the ionic/hydrophilic surfactant as part of Patel's composition.[4]

In addition, one of ordinary skill in the art would not have had any reason to pick a specific amount of phosphatidylcholine out of the teaching of Patel for combination with Zhang especially when Patel was concerned with achieving the appropriate combination of hydrophilic surfactants, lipophilic surfactants for delivery of an active agent and triglycerides whereas Zhang was concerned with choosing an appropriate dissolution agent, i.e. related to two different means of delivering an active agent. One of ordinary skill in the art would not have recognized that having at least 80% by weight of phosphatidylcholine was a requisite element of the invention and moreover would not have recognized that this element could be taken in isolation and combined with Zhang with a reasonable expectation of maintaining the successful use of Zhang's invention.

Therefore, the applicants' claims are not obvious over the cited references as all elements of the applicants' claims are not taught or suggested by the combination of Zhang, Patel, Weete, Steadman and Raisch when considered as a whole.

B. Claims 1, 6 and 7 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel"**) and Shen et al. (U.S. Patent 6,255,490 – **"Shen"**). The applicants request reconsideration of this rejection for the following reasons.

The rejection of claim 1 over Zhang and Patel has been addressed above and the use of Shen was primarily based on the reference to the use of epibatidine for combination with Zhang and Patel to address claim 7 and the rejection stands or falls with claim 1. Since claim 6 has been cancelled, this rejection has been rendered moot. The applicants reserve the right to further prosecute this subject matter in a continuation application.

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[4] The Office Action refers to Weete in an attempt to show that hydrogenated lecithins are within the context of the applicants' claimed invention. However, there is no reason why one of ordinary skill in the art would assume that the degree of conversion for the lecithins achieved in Weete was also the degree of conversion in Patel. Moreover, as noted above, lecithins are not the same as phosphatidylcholines which is even recognized by Patel (which recites phosphatidylcholines as a separate and distinct compound from lecithins and hydrogenated lecithins, see col. 31, line 23 and 38).

C. Claims 1 and 8 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel")** and Myer et al. (U.S. Patent 5,977,144 – **"Myer")**. The rejection of claim 1 over Zhang and Patel has been addressed above and the use of Myer was primarily based on the reference to the use of benzylidene- and cinnamylidene-anabasines for combination with Zhang and Patel to address claim 8. Since claim 8 has been cancelled, this rejection has been rendered moot. The applicants reserve the right to further prosecute this subject matter in a continuation application.

D. Claims 1 and 9 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel")** and **Cary** (U.S. Patent 6,197,827). The applicants request reconsideration of this rejection for the following reasons.

E. Claims 1 and 10 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel")** and Plotnikoff et al. (U.S. Patent 3,706,831 – "**Plotnikoff**"). The applicants request reconsideration of this rejection for the following reasons.

F. Claims 1 and 11 were rejected as allegedly being obvious by Zhang et al. (U.S. Patent 6,264,981 – **"Zhang") in view of** Patel et al. (U.S. Patent 6,248,363 – **"Patel")** and Serra et al. (*Eur. J. Pharmacol.* 2001 November; 430(2-3): 369-371 – "**Serra**"). The applicants request reconsideration of this rejection for the following reasons.

The rejection of claim 1 over Zhang and Patel has been addressed above and the use of Cary, Plotnikoff and Serra was primarily based on the reference to the use of the compounds of claims 9-11 for combination with Zhang and Patel to address claims 9-11 and the rejection stands or falls with claim 1.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/
Marilyn M. Brogan Howard C. Lee
Reg. No. 31,223 Reg. No. 48,104
Telephone: (212) 588-0800
Facsimile: (212) 588-0500